

Self-assessment of the outcome of early medical abortion versus clinic follow-up in India: a randomised, controlled, non-inferiority trial

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Summary

Background The need for multiple clinical visits remains a barrier to women accessing safe legal medical abortion services. Alternatives to routine clinic follow-up visits have not been assessed in rural low-resource settings. We compared the effectiveness of standard clinic follow-up versus home assessment of outcome of medical abortion in a low-resource setting.

Methods This randomised, controlled, non-inferiority trial was done in six health centres (three rural, three urban) in Rajasthan, India. Women seeking early medical abortion up to 9 weeks of gestation were randomly assigned (1:1) to either routine clinic follow-up or self-assessment at home. Randomisation was done with a computer-generated randomisation sequence, with a block size of six. The study was not blinded. Women in the home-assessment group were advised to use a pictorial instruction sheet and take a low-sensitivity urine pregnancy test at home, 10–14 days after intake of mifepristone, and were contacted by a home visit or telephone call to record the outcome of the abortion. The primary (non-inferiority) outcome was complete abortion without continuing pregnancy or need for surgical evacuation or additional mifepristone and misoprostol. The non-inferiority margin for the risk difference was 5%. All participants with a reported primary outcome and who followed the clinical protocol were included in the analysis. This study is registered with ClinicalTrials.gov, number NCT01827995.

Findings Between April 23, 2013, and May 15, 2014, 731 women were recruited and assigned to clinic follow-up ($n=366$) or home assessment ($n=365$), of whom 700 were analysed for the main outcomes ($n=336$ and $n=364$, respectively). Complete abortion without continuing pregnancy, surgical intervention, or additional mifepristone and misoprostol was reported in 313 (93%) of 336 women in the clinic follow-up group and 347 (95%) of 364 women in the home-assessment group (difference -2.2% , 95% CI -5.9 to 1.6). One case of haemorrhage occurred in each group (rate of adverse events 0.3% in each group); no other adverse events were noted.

Interpretation Home assessment of medical abortion outcome with a low-sensitivity urine pregnancy test is non-inferior to clinic follow-up, and could be introduced instead of a clinic follow-up visit in a low-resource setting.

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Introduction

Early first trimester medical abortion has been recognised as a safe and effective method for induced termination of pregnancy;^{1,2} however, it remains inaccessible for many women in low-resource settings. Reduced access to safe abortion leads women to seek unsafe abortion, an important cause of maternal mortality worldwide.³ In India, 8% of maternal deaths result from unsafe abortion; this proportion is slightly higher (10%) in the group of states that includes Rajasthan.⁴ An important factor affecting access and acceptability of medical abortion in women is the number of required clinical visits.^{5,6} The need for a routine follow-up visit to a clinic can be especially burdensome for women with low autonomy and limited financial resources, which is often the situation in low-resource settings. Furthermore, long travel time can result in lost wages and difficulties in ensuring privacy. Yet several clinical guidelines for

medical abortion require women to return for a follow-up visit.^{7,8}

Since women with post-abortion complications, if properly counselled, seek care before the routine follow-up visit,⁹ the main purpose of a routine follow-up visit after medical abortion is to detect a continuing pregnancy. Continuing pregnancies occur in 0.5–1.1% of women after first trimester medical abortion with mifepristone and misoprostol.^{10,11} A systematic review concluded that alternatives to routine in-person follow-up visits after medical abortion are accurate in diagnosing continuing pregnancies.¹² Technical and policy guidelines published by WHO recommend that there is no medical need for a routine clinic follow-up visit after medical abortion with mifepristone and misoprostol.² However, the quality of evidence underlying this recommendation is low and is mainly based on observational studies.

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In recent years, studies have assessed alternative methods of follow-up after medical abortion, such as use of a low-sensitivity urine pregnancy test, semiquantitative urine pregnancy test, or a high-sensitivity pregnancy test by women at home with follow-up by telephone call, text message, or online.^{13–21} These studies are mainly from high-resource settings, and depend on women having access to a telephone or the internet, and the ability to read. However, the situation in low-resource settings is different: large numbers of women reside in rural areas, have a low literacy level, and have limited access to telephone and transport facilities. Furthermore, there is no evidence to show that women with low literacy levels can take and interpret a pregnancy test at home.

The aim of this trial was to assess whether an approach of home assessment of medical abortion outcome is as effective in detecting ongoing pregnancy as a clinic follow-up visit in a low-resource setting.

Methods

Study design and participants

This study was a randomised, controlled, non-inferiority trial to assess the outcome of medical abortion with two methods of follow-up: routine clinic follow-up and self-assessment at home. The trial followed the CONSORT guidelines for non-inferiority randomised trials.²² The study protocol of this trial describes the methods in detail.²³ Women with unwanted pregnancies opting for medical abortion were eligible to participate in the study if their gestational age was 9 weeks or less as estimated by bimanual pelvic examination, if they resided in an area where follow-up was possible or they had access to a telephone on which they could talk privately, and who agreed to a follow-up after 2 weeks, by either telephone or home visit. A woman was ineligible if she had any contraindication to medical abortion, was younger than 18 years, or had a haemoglobin concentration of less than 85 g/L.

The study was done in three rural and three urban health centres in two districts of Rajasthan state in India. Of these, all three rural and one urban health centre were operated by a non-profit organisation, whereas two urban clinics were operated by single private doctors. The rural health centres were health facilities located 20–50 km from the district headquarters. All study clinics provided a range of reproductive health services, and specialists in obstetrics and gynaecology provided the abortion services in all clinics. In the state of Rajasthan, 75% of the population is rural, 48% of women are literate,²⁴ and an estimated 36% of women have the autonomy to travel alone.²⁵ In the study districts, 46% of people belong to underprivileged scheduled tribes or castes, and 30% of households owned a mobile telephone in 2007–08.²⁶

The study was approved by the institutional ethics committee of Action Research and Training for Health, Udaipur, India, and the regional ethics committee at Karolinska Institutet, Stockholm, Sweden. All women

gave written informed consent. Women were recruited between April 23, 2013, and May 15, 2014. The main outcome was measured 30 days after recruitment. One interim analysis was done halfway through the enrolment period and safety and efficacy was reviewed by a data and safety monitoring board.

Randomisation and masking

All eligible women who consented to participate in the study were randomly assigned (1:1) to one of two groups by a research assistant: clinic follow-up or home assessment. Randomisation was done with a computer-generated randomisation sequence, with a block size of six. The sequence was generated at the coordinating centre based in Udaipur, India. Sealed opaque envelopes containing the random allocation were numbered consecutively by an independent staff member at Udaipur, and were sent to the study sites. To avoid bias by clinical staff, randomisation was done after a decision was taken regarding place of misoprostol use (ie, at home or in the clinic). At each facility, research assistants were responsible for opening the envelopes and allocation of patients. Blinding of the groups from research assistants and clinical staff was not possible, since they were involved in instructing women about method of follow-up.

Procedures

All women with an unwanted pregnancy were first seen by doctors to assess their eligibility for medical abortion in terms of gestational age and contraindications. Women received routine counselling on method of abortion and contraception, and for women opting for medical abortion, a decision was made regarding place of misoprostol administration. Providers made a judgment regarding the place for misoprostol administration on the basis of their clinic's standard procedure and the woman's ability to reach a clinic within a reasonable time in the event of a complication. In cases in which there were no concerns, women were free to choose where to use misoprostol according to their preference. Providers at all sites followed their standard clinical procedures for medical abortion and no changes were made for the purpose of the study. Ultrasonography was not routinely used in five of the six study centres. The gestational age was estimated on the basis of bimanual examination by clinicians. After receiving mifepristone orally (200 mg), women were given instructions regarding the use of misoprostol (800 mcg, to be used 2 days later). The route of misoprostol administration differed across clinics as per their standard protocols and was sublingual (55%), vaginal (17%), or oral (28%).

Women in the clinic follow-up group were instructed to return for a visit 10–14 days after intake of mifepristone for clinical examination, and were offered a travel reimbursement (roughly US\$3·3). A doctor or nurse assessed the abortion outcome, did a low-sensitivity urine pregnancy test (Vedalab, Alençon, France; with a

अर्थ (सफल परिणाम)
महिला द्वारा घर पर मूल्यांकन हेतु चेकलिस्ट
पेशाब की जाँच कैसे करें?


क्लिनिक पर मोली लेने की तारीख


घर पर प्रेग्नेन्सी टेस्ट करने के निर्देश

1. हम आपको क्या-क्या दे रहे हैं-
 - प्लास्टिक का गिलास
 - पेशाब जाँच की पट्टी
 - ड्रॉपर
2. तारीख/वार को आपको पेशाब की जाँच करनी है।
3. पेशाब की जाँच कैसे करनी है-
 - पेशाब की जाँच गर्भसमापन के बाद 12 से 14 दिन के बाद करनी है।
 - इसके लिए प्लास्टिक के गिलास में बोझा सा पेशाब लें।
 - ड्रॉपर के एक छिदे को पेशाब में डालें व ऊपर छिदे को दबायें। इससे बोझ सा पेशाब ड्रॉपर में आ जायेगा।
 - पेशाब जाँच की पट्टी को खोलें व उसमें छिदे गये गोल भाग में पेशाब की 5-5 बूँदें डालें।
 - 10 से 20 मिनट तक इंतजार करें।


परिणाम


1. यदि लाल रंग की 2 या 3 लाईनें आती हैं तो इसका आशय है कि आपका गर्भसमापन पूर्ण हो गया है।





गर्भसमापन पूर्ण हो गया है
2. यदि लाल रंग की 4 लाईनें आती हैं, तो शायद आपका गर्भसमापन पूर्ण नहीं हुआ है और आपको तुरंत स्वास्थ्य केन्द्र जाने की आवश्यकता है।





गर्भसमापन पूर्ण नहीं हुआ है, स्वास्थ्य केन्द्र पर जायें।
3. यदि हल्की लाइनें भी हैं तो भी इसे लाइन माना जायेगा। अर्थात् यदि 3 गहरी लाइनें हैं और 1 हल्की लाइन है तो भी इसे चार लाइनें ही मानी जायेगी और भ्रूणविक पर वापस आयें।

किरण और प्रकाश के लिए नहीं है।

क्या आपको बिस्म में से कोई लक्षण है-

यदि आपको घर जाने के बाद बिस्मिडिजल में से कोई भी समस्या हो तो इसके लिये आपको 12-13 दिन तक इंतजार करने की जरूरत नहीं है। आप स्वास्थ्य केन्द्र पर तुरंत आइए-

1. क्या आपके बहुत अधिक बुलबुल आ रहे हैं?
(एक घंटे में 2-3 घंटे से ज्यादा भोजन) हाँ नहीं
2. क्या आपको (गोलियाँ लेने के 8 घंटे बाद भी) बुखार आया था/आयी है? हाँ नहीं
3. पेट में अत्यधिक तेज दर्द है? हाँ नहीं
4. क्या आपके अत्यधिक कमजोरी है? हाँ नहीं
5. क्या आपके पेशाब की जाँच घर बाहर लाइन (मोली लेने के 14 दिन बाद) आई? हाँ नहीं

इनमें से कोई भी लक्षण होने पर तुरंत अस्पताल जायें।
 यदि उपरोक्त में से कोई भी समस्या है तो तुरंत स्वास्थ्य केन्द्र पर सम्पर्क करें।

अर्थ स्वास्थ्य केन्द्र कुशीनी फोन नं. 9799087133	अर्थ स्वास्थ्य केन्द्र लखनवाली का गुड फोन नं. 9799498344	अर्थ स्वास्थ्य केन्द्र काँडवा फोन नं. 9799498346	अर्थ स्वास्थ्य केन्द्र पुला फोन नं. 9001999549	शैरस होस्पिटल विद्यामन के सामने फकापुरा फोन नं. 0294-2451013
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किरण और प्रकाश के लिए नहीं है।

Figure 1: Pictorial instruction sheet

serum human chorionic gonadotropin cutoff of 1000 IU/mL), and research assistants subsequently undertook the follow-up interviews.

Women in the home-assessment group were provided with a low-sensitivity urine pregnancy test to be done 10–14 days after the intake of mifepristone. They also received a pictorial instruction sheet (figure 1) with instructions on taking and interpreting the test, symptoms indicative of complications, and contact details of study clinics. Women were provided with detailed instructions verbally at the clinic on the use of the pregnancy test and were asked to return if they had any health problems or a positive or unclear test result. Follow-up interviews of women in the home-assessment group were done by home visits or a telephone call on day 12–15 after mifepristone, to screen for continuing pregnancies and complications. Some women who lacked privacy at home opted to come to the clinic after home assessment to report the outcome of their abortion and the result of the pregnancy test. Three attempts were made to contact women, up to 30 days after intake of mifepristone, after which they were considered lost to scheduled follow-up. Strict attention was paid to confidentiality during home visits and telephone calls.²² Women who reported the outcome of pregnancy tests as positive or “not sure”, or who had symptoms suggestive

of complications, were referred to the clinic. If the woman had not done the pregnancy test by the time of the follow-up interview, the research assistant reminded her to do the test and interpret the result herself.

Women detected to have a continuing pregnancy or incomplete abortion received surgical evacuation or additional mifepristone and misoprostol. Clinical records of all women presenting for interim visits (defined as visits by women between the day of misoprostol administration and scheduled follow-up contact at the clinic or by the research assistant) were checked to record the outcome of abortions and the procedures performed. Women in the clinic follow-up group who did not return for their follow-up visit or women in the home-assessment group who had a positive or “not sure” pregnancy test but did not return to the clinic, were later contacted by the research assistants by telephone call or home visit. Information was gathered on return of menses, continuing pregnancy, any surgical intervention, treatment for completion of abortion at another clinic, or complications (hospital admission, intravenous fluids, blood transfusion).

Outcomes

The primary outcome measure was efficacy, defined as complete abortion without continuing pregnancy or the need for surgical intervention or additional mifepristone

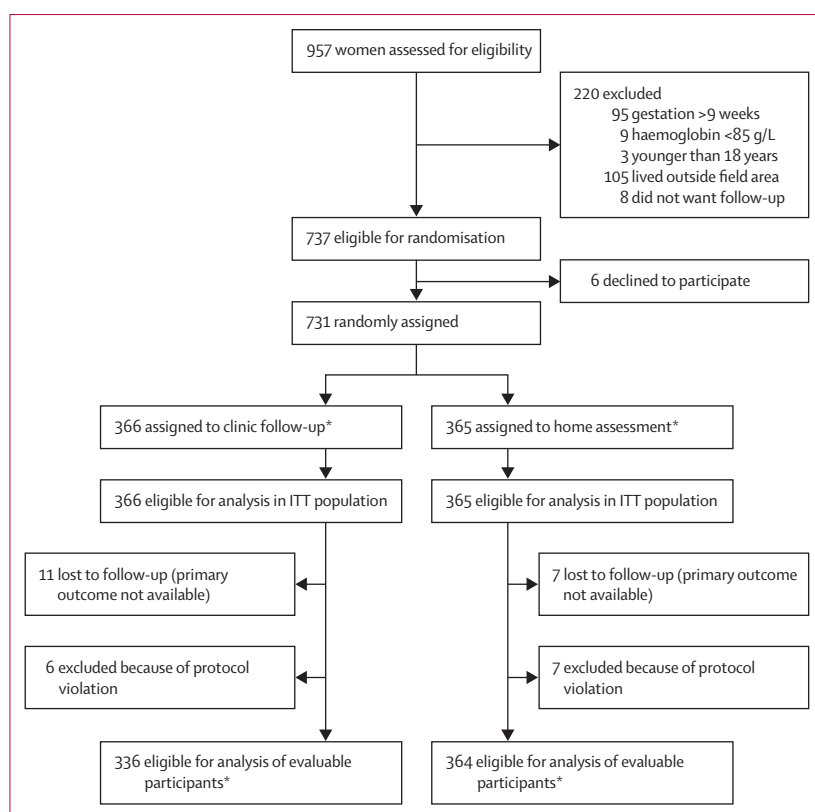


Figure 2: Trial profile

*15 women who were in the clinic follow-up group as per the randomisation list received home assessment, and two women who were in the home-assessment group as per the randomisation list received clinic follow-up.

and misoprostol. Secondary outcomes were safety (defined as no adverse events requiring hospital admission, blood transfusion, intravenous fluids, or intravenous antibiotics) and feasibility (defined as ability of women to take the low-sensitivity urine pregnancy test on their own, to determine the outcome of abortion). The outcomes were measured by questionnaires administered at follow-up. Clinical records were reviewed for women who made interim visits. Additionally, we compared reasons for interim visits between groups.

Statistical analysis

To test the hypothesis that home assessment of outcome of abortion would be as effective as clinic follow-up, we set the margin of non-inferiority to an absolute difference between groups of five percentage points in the rate of unsuccessful abortions. The rate of complete abortion with mifepristone and misoprostol reported in practice is 95%,¹¹ and we based this cutoff on what we deemed to be a clinically important difference and on ethical criteria, cost, and feasibility. Hence, we aimed to prove that the rate of complete abortion is at most 5% lower in the home-assessment group than in the routine follow-up group.

On the assumption that 5% of women would have unsuccessful abortions (continuing pregnancies or

incomplete abortions) after medical abortion with routine follow-up,¹¹ a sample size of 596 women was calculated to be sufficient (with a two-sided 95% CI and 80% power) to establish non-inferiority of the intervention. We allowed for 20% loss to follow-up, and planned to recruit 716 women.

Data entry was done at the coordinating centre in India. All statistical calculations were made with SPSS (version 22) and in R (version 3.0.3). Categorical variables are presented with descriptive statistics and were compared with χ^2 tests. Continuous data were presented as mean (SD) and compared with t tests. p values less than 0.05 were considered statistically significant.

We identified two study populations: the intention-to-treat (ITT) population (all randomly assigned women as per the randomisation list, irrespective of actual allocation) and evaluable participants (those actually allocated to the study groups, with a reported primary outcome, and who followed the clinical protocol). Hence, the evaluable population consisted of all women who took mifepristone and misoprostol, and for whom outcome information was available either through scheduled follow-up contacts, through later contacts, or through records of interim visits. Our analysis and interpretation of the primary outcome is based on the evaluable population.

Since information about the primary outcome was missing for 18 women in the ITT population, we did two sensitivity analyses in which the missing values were imputed: one assuming that all women with missing values had successful abortions and one assuming that all women with missing values had unsuccessful abortions. This study is registered with ClinicalTrials.gov, number NCT01827995.

Role of the funding source

The funders of the study were not involved in study design, data collection, data analysis, data interpretation, or writing of the report. All authors had full access to the data in the study. The corresponding author had final responsibility for the decision to submit for publication.

Results

Figure 2 shows the trial profile. 731 eligible women consented and were randomly assigned to clinic follow-up ($n=366$) or home assessment ($n=365$). At the time of analysis, we detected that 15 women in the clinic follow-up group as per the randomisation list were allocated to the home assessment group, and two women in the home assessment group as per the randomisation list were allocated to the clinic follow-up group because of an error in randomisation by research assistants. However, comparison of results between the two groups as per randomisation list did not show any significant differences in characteristics or outcomes (table 1). Most women (73%) lived in a rural area, 56% belonged to scheduled castes or tribes, and 45% were literate.

	Clinic follow-up group (n=353)	Home-assessment group (n=378)
Mean age (years)	27.22 (4.9)	26.98 (4.78)
Residence		
Urban	100 (28%)	99 (26%)
Rural	253 (72%)	279 (74%)
Caste		
Scheduled tribes or castes	192 (54%)	218 (58%)
Others	161 (46%)	160 (42%)
Level of education		
No formal education	183 (52%)	222 (59%)
Lower than primary	61 (17%)	52 (14%)
Primary	68 (19%)	59 (16%)
Secondary or above	41 (12%)	45 (12%)
Paid employment		
Yes (daily wages/salaried/business/other)	59 (17%)	74 (20%)
No (housewife/farmer)	294 (83%)	304 (80%)
Ownership of telephone		
Self	164 (46%)	160 (42%)
Husband	123 (35%)	146 (39%)
Other family members or none	66 (19%)	72 (19%)
Gestational age (weeks)		
<6	67 (19%)	61 (16%)
6–7	194 (55%)	213 (56%)
8–9	92 (26%)	104 (28%)
Previous births		
0	16 (5%)	20 (5%)
1–2	201 (57%)	212 (56%)
3 or above	136 (39%)	146 (39%)
Previous induced abortion	121 (34%)	116 (31%)
Type of previous induced abortion*		
Previous medical abortion	90 (25%)	92 (24%)
Previous surgical abortion	36 (10%)	29 (8%)
Place of misoprostol use		
Home	170 (48%)	172 (46%)
Clinic	183 (52%)	206 (54%)

Data are mean (SD) or n (%). *Some women reported several types of abortion.

Table 1: Background characteristics as per study group allocation

Adherence to scheduled follow-up contact was lower in the clinic follow-up group (274 [78%]) than in the home-assessment group (349 [92%]; table 2). In the home-assessment group, 267 (77%) women were followed up by home visits, 65 (19%) by telephone calls, and 17 (5%) by clinic visit. 128 women made an interim visit, and of these, clinical outcomes were determined for 110 women. Of the women who had neither a scheduled follow-up contact nor an interim visit, outcome information was obtained for 70 women by home visits or telephone calls. 13 women (six in the clinic follow-up group and seven in the home-assessment group) did not use misoprostol and were excluded from the analysis, and 18 women (11 in the clinic follow-up group and seven in the home-assessment group) were lost to follow-up (figure 2).

	Clinic follow-up group (n=353)	Home-assessment group (n=378)
Number having scheduled follow-up contact	274 (78%)	349 (92%)
Number who did not use misoprostol or were lost to follow-up	17 (5%)	14 (4%)
Evaluable population*	336 (95%)	364 (96%)
Method of outcome determination in evaluable participants		
Interim visits†	48 (14%)	62 (17%)
Scheduled follow-up contacts	232 (69%)	288 (79%)
Later contacts for outcome information	56 (17%)	14 (4%)

*Number of women who used misoprostol and whose outcome information is available. †Apart from seven women (six in clinic follow-up group and one in the home assessment group), all other women with interim visits also had a scheduled follow-up contact.

Table 2: Adherence to trial procedures and mode of outcome determination

	Clinic follow-up group	Home-assessment group	Difference in outcome rates (95% CI)
ITT analysis*	366	365	..
Complete abortion	340 (93%)	347 (95%)	-2.2% (-5.9 to 1.5%)
Unsuccessful abortion	26 (7%)	18 (5%)	..
Continuing‡	7 (2%)	3 (1%)	..
Continued the pregnancy	3	1	..
Surgical evacuation	3	2	..
Repeat medical abortion	1	0	..
Incomplete‡	19 (5%)	15 (4%)	..
Surgical evacuation	15	12	..
Repeat misoprostol	4	3	..
Evaluable population analysis§	336	364	..
Complete abortion	313 (93%)	347 (95%)	-2.2% (-5.9 to 1.6%)
Unsuccessful abortion	23 (7%)	17 (5%)	..
Continuing	5 (1%)	2 (1%)	..
Continued the pregnancy	1	0	..
Surgical evacuation	3	2	..
Repeat medical abortion	1	0	..
Incomplete‡	18 (5%)	15 (4%)	..
Surgical evacuation	14	12	..
Repeat misoprostol	4	3	..
Lost to follow-up	11	7	..
Violation of protocol	6	7	..

Data are number of women or n (%), unless otherwise stated. *For the intention-to-treat (ITT) analysis, the groups were analysed as per the randomisation list and with imputed success where outcome was unknown. †The three additional continuing pregnancies in the ITT analysis were in women who did not use misoprostol, hence these were protocol violations. ‡Incomplete abortions were defined as diagnosis of retained products of conception with need for surgical intervention or additional misoprostol. §For the evaluable population analysis, the groups were analysed as per actual allocation.

Table 3: Outcome of medical abortion for intention-to-treat population and evaluable population

700 women (clinic follow-up, n=336; home assessment, n=364) were therefore evaluable and included in the analysis of the primary outcome.

In the analysis of evaluable participants, complete abortion was reported in 313 (93%) of 336 women in the clinic follow-up group and 347 (95%) of 364 women in the home-assessment group (risk difference -2.2%, 95% CI -5.9 to 1.6; table 3, appendix). In the ITT

See Online for appendix

	Clinic follow-up group (n=336)	Home-assessment group (n=364)
Ongoing pregnancy	5 (1%)	2 (1%)
Interim visit	3 (1%)	1 (<1%)
Scheduled visit to the clinic	2 (1%)	1 (<1%)
Incomplete abortion	18 (5%)	15 (4%)
Interim visit	10 (3%)	11 (3%)
Scheduled visit to the clinic	8 (2%)	4 (1%)
All unsuccessful abortions	23 (7%)	17 (5%)
Interim visit	13 (4%)	12 (3%)
Scheduled visit to the clinic	10 (3%)	5 (1%)

Data are n (%).

Table 4: Timing of outcome determination

	Clinic follow-up group (n=336)	Home-assessment group (n=364)
Serious adverse events		
Haemorrhage requiring intravenous fluids	1 (<1%)	1 (<1%)
Haemorrhage requiring blood transfusion	1 (<1%)	0
Infection requiring intravenous antibiotics	0	0
Hospital admission	1 (<1%)	0
Side-effect reported to follow-up contact*	274	349
Any side-effect reported to follow-up contact (multiple responses possible)	47 (17%)	49 (14%)
Excessive bleeding	9 (3%)	24 (7%)
Severe abdominal pain	12 (4%)	19 (5%)
Feels unwell	14 (5%)	13 (4%)
Had fever	24 (9%)	19 (5%)

Data are number or n (%). *Information about side-effects is available for 619 women who had a scheduled contact.

Table 5: Adverse events and side-effects

population, when success was imputed for unknown outcomes, complete abortion was reported in 340 (93%) of 366 women in the clinic follow-up group and 347 (95%) of 365 in the home-assessment group (risk difference -2.2% , 95% CI -5.9 to 1.5). For the primary outcome, the upper limit of the 95% CI lies within the non-inferiority margin (5%) for both ITT and evaluable population analyses.

The sensitivity analysis for the ITT population did not alter the results when imputing failure (data not shown). In the analysis with adjustment for caste, residence, education, employment, and place of misoprostol use, there was no difference in the rate of complete abortion between clinic follow-up and home-assessment groups. However, complete abortions were correlated with residence in a rural area and belonging to scheduled tribes or castes (data not shown).

In the ITT population, there were seven continuing pregnancies in the clinic follow-up group and three in the home-assessment group; in the evaluable population, there were five and two continuing pregnancies, respectively. After imputation of a complete abortion

outcome to all women who were lost to follow-up, the overall ITT complete abortion rate was 94% and continuing pregnancy rate was 1%. In the analysis of evaluable participants, the overall rates of complete abortion, incomplete abortion, and continuing pregnancy were 94%, 5%, and 1%, respectively (table 3). Of the seven continuing pregnancies in the evaluable population, four were detected by interim visits on day 6 or later, whereas three were detected by scheduled visits (table 4). 22 (7%) women in the clinic follow-up group and 17 (5%) women in the home-assessment group had surgical intervention or additional mifepristone or misoprostol or both; however, the difference between groups was not statistically significant.

One woman in the clinic follow-up group needed blood transfusion and admission to hospital for haemorrhage, and one woman in the home-assessment group needed intravenous fluids for haemorrhage. Overall, the rate of adverse events in our study was 0.3% (table 5). 95 (15%) of 619 women who had a scheduled follow-up reported other side-effects (heavy bleeding, severe abdominal pain, fever, or feeling unwell). Of 128 women who sought care at interim visits, nearly half (n=62) visited because of a symptom suggestive of an abortion complication (appendix); the remaining interim visits were related to contraception or to concerns about completion of abortion. Most interim visits occurred between the day of misoprostol administration and scheduled follow-up contact (between days 4 and 14 [116 (91%)]).

Of the 289 women in the home-assessment group whose outcome was not identified by an interim visit, 233 (81%) took their low-sensitivity urine pregnancy test before being contacted by the research assistant, 54 (19%) did it after being reminded by the research assistant, and two women (1%) did not do the test (table 6). Most of the women who took the test after being reminded by the research assistant interpreted the result themselves. 15 (5%) women who took the pregnancy test had a positive result or were unsure of their result, and were asked to return to the clinic. Among the 11 women who returned to the clinic, there was one continuing pregnancy and three incomplete abortions. Of 272 women with a negative test result, 25 had some concerns or symptoms suggestive of complications, and were advised to return to the clinic. Ten of these women complied with the advice and returned to the clinic and one was diagnosed as having incomplete abortion. Women who did not do the low-sensitivity urine pregnancy test or who had a positive or "not sure" test result, and did not return to the clinic, were subsequently contacted and all reported complete abortions. 229 (98%) women who did the test on their own reported that it was easy to use. Women were less likely to take the test if they had reported a side-effect (20/33 [61%]) versus if they had not reported a side-effect (213/256 [83%]); lived in a rural area (162/211 [77%]) versus urban area (71/78 [91%]); belonged to a scheduled tribe or caste (123/165 [75%]) versus those belonging to other

	Number of women (n=289)*
Did LSUP test on her own without reminder	233 (81%)
Ease of doing the LSUP test (in women who did it without reminder)	
Easy	229 (98%)
Difficult	4 (2%)
Reasons for not doing the LSUP test on her own	
Forgot, was planning to do it in a day or two, or was waiting for research assistant	18 (32%)
Difficult to do or no privacy	18 (32%)
Went out of house (to attend a social function or to parents' home) or lost LSUP card	7 (13%)
Did not think it was needed	4 (7%)
Bleeding continued or ill	8 (14%)
Did LSUP test after reminder by research assistant	54 (19%)
Did not do LSUP test at all	2 (1%)
Woman looked at pictorial instruction sheet	225 (78%)
Result of LSUP test (n=287)	
Positive	12 (4%)
Not sure	3 (1%)
Negative	272 (95%)
Referred to the clinic by research assistant	
Yes	40 (14%)
No	249 (86%)
Women who screened positive on LSUP test and referred to the clinic (n=15)	
Returned to the clinic	11/15 (73%)
Did not return to the clinic	4/15 (27%)
Women who screened negative on LSUP test or did not do the LSUP test and referred to the clinic (n=25)	
Returned to the clinic	10/25 (40%)
Did not return to the clinic	15/25 (60%)
Data are n (%). LSUP=low-sensitivity urine pregnancy. *Data exclude all women whose abortion outcome was determined on interim visits.	

Table 6: Characteristics of home-assessment group

castes (110/124 [89%]), and were illiterate (121/157 [77%]) versus literate (112/132 [85%]). Most women in the clinic follow-up group (262/274 [96%]) and home-assessment group (334/349 [96%]) were satisfied with the method of abortion follow-up.

In the 515 women from both groups who were successfully contacted, whose abortion outcome was not determined by interim visits, and whose pregnancy tests were done, two continuing pregnancies and no false-negative tests were identified. Hence the sensitivity of the low-sensitivity urine pregnancy test to detect continuing pregnancy was 100% (95% CI 19.7–100) and specificity was 94.5% (92.1–96.2). The negative and positive predictive values were 100% (99.0–100) and 6.7% (1.2–23.5), respectively.

Discussion

Our findings suggest that home assessment with a low-sensitivity urine pregnancy test is an effective alternative to clinic follow-up after early medical abortion, and that

women can take and interpret a low-sensitivity pregnancy test even in low-resource settings. Although our study was not powered to establish safety of home assessment, it shows a very low rate of adverse events in line with previous studies that have reported rates of between 0.11% and 0.16%.^{27,28} Thus, we infer that home assessment is an effective and safe alternative to clinic follow-up after early medical abortion. Two other randomised controlled trials have compared self-assessment with clinic follow-up visits. However, there are important contextual differences between these trials and ours: the trial in Vietnam recruited only women who were literate, able to complete an at-home symptom checklist, and who had a personal telephone. Further, it used a semiquantitative pregnancy test followed up with a telephone call.¹⁹ Similarly, in a trial from Europe that used the same low-sensitivity urine pregnancy test with a 1000 IU/L cutoff for self-assessment, women were followed up by telephone call, were educated, and their gestational age was identified by ultrasound.¹⁶ In our study, more than half the participants were illiterate and did not own a telephone, and most of the women in the home-assessment group were followed up with a home visit. Despite these differences, our findings correspond well with previous trials showing that self-assessment was non-inferior to clinic follow-up and is as feasible in these settings.

In our study, fewer continuing pregnancies were detected in the home-assessment group than in the clinic follow-up group. However, we believe that this difference was by chance and not because we missed any continuing pregnancies, since the overall loss to follow-up was very low (2.5%) in the whole study, and even lower in the home-assessment group (1.9%). Furthermore, more incomplete abortions were detected in the clinic follow-up group than in the home-assessment group at scheduled follow-up. The difference was not statistically significant but indicates a trend, and could result from providers' greater propensity to intervene during clinic visits. A study concluded that the differences in surgical intervention rates after medical abortion are likely to be caused by different clinical practices and local guidelines, rather than genuine need for surgical intervention.²⁹ Thus, a scheme based on home assessment is likely to prevent the unnecessary surgical interventions and ultrasounds that might be done at clinic follow-up visits.

In our study, about two-thirds of unsuccessful abortions were detected by interim visits. Other studies have also shown that complications and incomplete abortions rarely occur at the time of scheduled follow-up visits and call for unscheduled visits.⁹ However, the reliance on symptoms alone has not been shown to be a precise method of follow-up after medical abortion,¹² hence an objective measure to detect continuing pregnancies is still needed.

We chose to use a low-sensitivity urine pregnancy test with a 1000 IU/L cutoff in this study because it has been shown to be effective in previous studies,^{14,15} and is a

Panel: Research in context**Systematic review**

We searched Web of Science and PubMed between May 28, 2014, and Sept 5, 2014, with the search terms “medical abortion”, “induced abortion”, “follow up”, and “simplified” for studies and systematic reviews assessing follow-up after medical abortion. There were no language restrictions. We identified two randomised controlled trials^{16,19} and several observational studies^{13–15,17,18,20,30} that have assessed alternative methods of follow-up. All these studies were either from high-resource settings or recruited women who were educated and had a personal telephone. The results of these studies show that alternative methods of follow-up after medical abortion are feasible and effective to screen for continuing pregnancies.

Interpretation

Our study suggests that home assessment of outcome of abortion is non-inferior to clinic follow-up after early medical abortion. This study provides the only evidence thus far from a low-resource rural setting that women with low literacy can feasibly assess the outcome of an early medical abortion. Taken together, these studies provide evidence that service delivery guidelines on medical abortion should consider substituting a clinic follow-up visit with home assessment with an appropriate low-sensitivity urine pregnancy test and a user-friendly pictorial guide.

simple test with two columns, which is likely to be better interpreted by women with low literacy than the semiquantitative pregnancy test, which has five columns. Use of a high-sensitivity pregnancy test at 1 month would delay the detection of continuing pregnancies and in the event of a continuing pregnancy, women would find it difficult to obtain abortion service in a primary care setting. In our study, 80% of women did the pregnancy test on their own, and nearly all found it easy to do. Our finding that more than three-quarters of rural and illiterate women were able to do their low-sensitivity urine pregnancy test suggests that home assessment is feasible even in low-literacy rural settings. Discussions with our team showed that the design of the study protocol, in which all women were informed that a research assistant would visit them, might have led some of the women to think that they were meant to wait for this visit before taking the pregnancy test. We expect that if this intervention is implemented in the health system, a greater proportion of women will do the test without need for the reminder.

Women in low-resource settings may especially benefit from home assessment, since their autonomy to travel is low, financial resources are meagre, and transport options are scarce and time consuming. The need for multiple clinic visits might raise concerns about privacy, child care, and lost wages, and may deter women from seeking safe abortion services. Home assessment enabled 75% of women to avoid a clinic visit, and hence introduction of a system of home assessment could lead to substantial reductions in the costs of clinic follow-up visits for women and health systems. Furthermore, since clinic follow-up rates after medical abortion tend to be low anyway,⁹ home assessment would allow a greater proportion of women to determine their abortion

outcome. Allowing home assessment would give women greater autonomy in managing the abortion process, seeking care only when needed and still allowing them to know their abortion outcome. Furthermore, we suggest that, irrespective of the system of follow-up, counselling on danger signs and symptoms suggestive of continuing pregnancy should be routinely provided on the day of mifepristone intake.

The external validity and applicability of the findings of our study are very high. The socioeconomic and demographic characteristics of study participants represent women living in underserved areas of the country and reflect the composition of the general population in this area. Additionally, the rural health centres were small health facilities located in remote areas, whereas the urban health centres were single provider operated clinics, representative of typical health facilities providing abortion services.

The introduction of a system of home assessment as a replacement for routine clinic follow-up can be explored in health systems. The scheme of home assessment would mean that women are supplied with low-sensitivity urine pregnancy test kits, containers for collecting urine, and pictorial instruction sheets, on the day of mifepristone intake. Furthermore, providers assisting with abortion care need to counsel the women on how to take and interpret the test, and seek care for complications—this task can be done by existing mid-level providers or by non-medical staff in health facilities. Additionally, the provider time spent on routine clinic follow-up visits would be saved. Some studies have used follow-up by telephone call with a symptom checklist along with self-assessment with a low-sensitivity or high-sensitivity pregnancy test.^{14,15,18–20} However, in our setting, most women do not own a telephone and hence telephonic interviews or reminders would not be feasible. Additionally, home visit by a health worker could raise serious confidentiality problems; therefore, home assessment by women themselves without follow-up by telephone call or home visit would be most appropriate in the current scenario.

The low-sensitivity urine pregnancy test has a high negative predictive value for detection of continuing pregnancies, and hence the risk of missing a continuing pregnancy is extremely low. Although some women with a positive low-sensitivity urine pregnancy test despite a complete abortion would need to return to the clinic, it still diminishes the need for a clinic visit for most women. Currently, low-sensitivity urine pregnancy tests are commercially available in Europe, but not in other settings. These tests are not yet a part of routine abortion care; therefore, their development and production will have to be promoted by policy makers if they are recommended for follow-up after medical abortion. Experience with high-sensitivity pregnancy tests, which are widely available at low cost in India, shows that if low-sensitivity pregnancy tests were to be widely promoted,

produced, and marketed in low-resource countries, they could be introduced affordably.

In conclusion, home assessment with a low-sensitivity pregnancy test is a feasible and effective method to identify women with continuing pregnancy after early medical abortion, even for women living in remote areas of developing countries (panel). In areas where an additional visit to the clinic could deter women from seeking services from safe legal providers, reducing the need for a routine follow-up visit would increase access for women to safe abortion services, and contribute to a reduction in abortion-related maternal mortality.

Contributors

KI participated in study design, development of the protocol, and implementation of the study, oversaw data management, analysed the data, and drafted the report. MP participated in study design, development of the protocol, implementation of the study, data management, data analysis, and contributed to drafting of the report. SDI was co-principal investigator, participated in conceptualising the study, provided guidance and oversaw implementation of the trial and data analysis, and contributed to interpretation of results and drafting of the report. MK-A participated in conceptualising the study, development of the protocol, was responsible for the conduct of the trial and analyses, and contributed to drafting of the report. BE participated in development of the protocol and study design, and contributed to drafting of the report. JB was the statistician of the study and participated in data analysis and reporting. SS participated in implementation of the study, data management, and interpretation of findings. KG-D was the principal investigator, conceptualised and designed the study, was responsible for the overall conduct of the trial, data analysis, interpretation of results, and contributed to drafting of the report. All authors have had access to the data, contributed to writing of the report, and approved the final submitted version.

Declaration of interests

We declare no competing interests.

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